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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,212

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Kazuhiro Fukae

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KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

ARIANI, KADE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,212	Applicant(s) FUKAE, KAZUHIRO	
	Examiner KADE ARIANI	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on April 07, 2008, has been received and entered.

Claims 1-12 are pending in this application and were examined on their merits.

Declaration under 37 C.F.R. § 1.132

The declaration under 37 CFR 1.132 filed on 04/07/2008 is insufficient to overcome the rejection of claims under 35 U.S.C. 103(a)1-12 as being unpatentable over Koketsu et al. (The journal of Food Science, 1993, Vol. 58, No. 4, p.743-747) and Inazu et al. (in IDS, Peptide Science 1998, M. Kondo Edition, p. 153-156) and in view of Yamamoto, K. (Journal of Bioscience and Bioengineering, 2001, Vol. 92, No. 6, p.493-501), as set forth in the last Office action because:

An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In this case the declaration compares the subject matter of Examples 1 and 2 in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koketsu et al. (The Journal of Food Science, 1993, Vol. 58, No. 4, p.743-747) and Inazu et al. (in IDS, Peptide Science 1998, M. Kondo Edition, p. 153-156) and in view of Yamamoto, K. (Journal of Bioscience and Bioengineering, 2001, Vol. 92, No. 6, p.493-501), and further in view of Stedman's Medical Dictionary 27th Edition.

Claims 1-12 are drawn to a process for preparing asparagine-linked oligosaccharide derivatives including the steps of (a) treating a delipidated egg yolk with a protease (b) treating with a peptidase to obtain a mixture of asparagine-linked oligosaccharides, (c) introducing a lipophilic protective group into the asparagine-linked oligosaccharides, and (d) subjecting the mixture of asparagine-linked oligosaccharide derivatives to a fractionating chromatography using a reverse phase column to separate the mixture, delipidating an avian egg yolk with an organic solvent, penta- (hepta-, nona-) to undecasaccharide derivatives, the lipophilic protective group is a carbonate-containing group, the lipophilic protective group is Fmoc group, the asparagine-linked oligosaccharides obtained by step (b) are hydrolyzed before the subsequent step to cut off some sugar moieties, the asparagine-linked oligosaccharides obtained in the mixture by step (c) are hydrolyzed before the subsequent step to cut off some sugar moieties.

Koketsu et al. teach a process for preparing asparagine-linked oligosaccharide derivatives, treating an avian egg yolk with ethanol (organic solvent) to obtain

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delipidated egg yolk (DEY), and separating the mixture of oligosaccharides by reverse-phase column, the oligosaccharide derivatives are hydrolyzed to cut off some sugar moieties, and a undecasaccharide derivative (p.743, Abstract, and 2nd column, 3rd paragraph, lines 1-2, p. 744, 2nd column 4th paragraph, lines 1-5, p. 746, Figure 5, 3rd oligosaccharide derivative).

Koketsu et al. further teach liberating asparagine-linked oligosaccharides from protein by hydrazinolysis, and further teach investigation of the biological function of cell surface oligosaccharides requires efficient methods for preparation of a variety of surface oligosaccharides especially sialyloligosaccharides, and chemical and enzymatic methods are being explored (p.743 1st column 2nd paragraph).

Koketsu et al. do not teach treating with a protease (or a peptidase). However, Inazu et al. teach a process for preparing asparagine-linked oligosaccharide derivatives, treating a egg with Pronase (a protease), introducing a lipophilic protective group into the asparagine-linked oligosaccharides, and subjecting the mixture of asparagine-linked oligosaccharide derivatives to a fractionating chromatography using a reverse phase column to separate the mixture, and a penta- to undecasaccharide derivatives (p. 153, Abstract and p. 154, figure 1.).

Further motivation to use proteases in a process for preparing asparagine-linked oligosaccharides is in Yamamoto who teaches using peptidases in the synthesis of asparagine-linked oligosaccharides. Yamamoto teaches oligosaccharide moieties of some glycoconjugates have been shown to play important roles in biological phenomena such as cellular recognition, lectin binding, and viral infection, among

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others. The synthesis of new oligosaccharide with additional functions by modification of naturally occurring oligosaccharides, and the addition of an oligosaccharide to a substance to give it a useful function are important subjects in glycotechnology.

Chemical synthesis of oligosaccharides are labor-intensive and involve complicated steps, on the other hand, enzymatic methods have the advantages because of their high stereo- and regio-selectivities (p. 493 Introduction 1st column, 1st paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art to combine the prior art teachings and to modify and improve the method as taught by Koketsu et al. according to the teachings of Inazu et al. by using proteolytic enzymes (protease or peptidase) to release asparagine-linked oligosaccharides from delipidated egg yolk and to provide a process for preparing asparagine-linked oligosaccharide derivatives. As disclosed in Yamamoto et al. the motivation would be the advantages of enzymatic methods (high stereo- and regio-selectivities) over chemical synthesis.

Applicant's arguments filed on 04/07/2008 have been fully considered but they are not persuasive.

Applicant argues that there is no proper motive to make the specific modification to the art that has proposed, and the proposed modification would provide reasonably expected results.

Applicant argues that it is essential to use a delipidated egg yolk and to use a combination of a protease and a peptidase.

Please note that protease and peptidase are generic for proteolytic enzymes (Stedman's Medical Dictionary 27th Edition).

The claimed method would have been obvious because one of ordinary skill in the art could have combined the prior art teachings and use enzymatic liberation (proteolysis) of asparagine-linked oligosaccharide from delipidated egg yolk instead of chemical liberation (hydrazinolysis), and the combination would have yielded the predictable results of liberating asparagine-linked oligosaccharide derivatives from proteins in the delipidated egg yolk to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Kade Ariani
Examiner
Art Unit 1651